

REMARKS

Upon entry of the Amendment above, claims 1-23 will be pending in this application. Reconsideration of the merits of the application is respectfully requested in light of the Amendment above and the Remarks that follow.

Objections to Drawings

The Examiner objected to the drawings because reference character 56 in Figure 4 was not mentioned in the description. Paragraph [0036] of the Specification has been amended to include mention of reference character 56 in the discussion of the process described in Figure 4.

Objections to the Specification

The Examiner objected to the use of the trademarks “SynchroMed” and “Medtronic, Inc.” where the marks were not capitalized. Applicant has amended paragraph [0039] of the Specification to indicate that the word “SynchroMed” is a trademark by capitalizing the word. Applicant submits that as used in the Specification the words “Medtronic, Inc.” are not used as a trademark in the Specification but to indicate the fact that the pump systems commercially sold under the SYNCHROMED trademark are available from the company Medtronic, Inc. The location of the company has been added to the Specification after the words “Medtronic, Inc.” in order to clarify that the word “Medtronic” is not being used as a trademark in the Specification.

Claim Objections

The Examiner has objected to claim 16 and 22 for certain informalities. The claims have been amended to correct the informalities. Applicant requests that this objection be withdrawn.

§ 102 Rejection of the Claims

Claims 1-4, 6, 8, 9, 11-17, 23 and 24 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Clegg et al., U.S. Patent No. 4,823,808. Applicant respectfully traverses this rejection.

Applicant has amended claim 1 to include the step of implanting in the patient an implantable medical device comprising a memory and a processor where the sensed physiological parameters are supplied to the implanted medical device and the communication to

the patient is generated by the processor of the implanted device. Clegg et al. do not teach the use of a processor in an implanted medical device. The data processor of Clegg et al. is located outside of the patient's body. Because Clegg et al. do not disclose implanting a medical device comprising a processor that receives the sensed physiological parameter and generates a communication to the patient as a function of such sensed physiological parameter, it does not anticipate claim 1, and therefore it also does not anticipate those claims dependent thereon, claims 2-4 and 6. Accordingly, withdrawal of the rejection of those claims is respectfully requested.

Applicant has amended claim 8 to indicate that the processor is programmable and includes programmed instructions and that the processor is a component of an implantable medical device. Clegg et al. do not disclose a programmable processor or an implantable medical device and therefore the teachings thereof do not anticipate claim 8 or those claims dependent thereon, claims 9, and 11-17. Accordingly, withdrawal of the rejection of those claims is respectfully requested.

Applicant has amended claim 23 to include processing instructions for measuring a first characteristic of the sensed physiologic parameter and a second characteristic of a second physiological parameter of a second physiological parameter as a function of the first characteristic. Clegg et al. do not disclose this feature and therefore the teachings thereof do not anticipate claim 23. Accordingly, withdrawal of the rejection of claim 23 is respectfully requested.

Claims 8 and 18-22 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Foley et al., U.S. Patent Publication No. 2002/0072780A1. Applicant respectfully traverses this rejection.

The Examiner takes the position that Foley et al. teach a system that includes a sensor to monitor gastric electrical activity and a processor that generates a communication to the patient as a function of the sensed physiological parameter and "communication means to notify a patient of the communication." Applicant disagree that the system described in Foley et al. includes a processor that generates a communication to the patient as a function of the sensed physiological parameter or communication means to notify a patient of the communication. The system of Foley et al. as described in paragraphs [0038] and [0039] includes a sensor to sense intrinsic gastric electrical activity, identify if the activity is normal or abnormal and a processor

that generates a signal to an implantable gastric stimulator instructing the stimulator to apply electrical stimulation to the patient to disrupt it. Nowhere is it suggested or described in those paragraphs that the processor will generate a communication to the patient notifying the patient that a change has occurred in the activity of the stomach as a function of a change in the sensed physiological parameter. The Examiner suggested that a “communication means to notify a patient of the communication” was described in paragraph [0061]. Applicant does not see any teaching in that paragraph or elsewhere in the reference that the system includes a communication means to notify a patient of the communication. The paragraph describes an external programmer that is an interface between the physician and the implantable gastric stimulator and describes means whereby the physician may receive information about the device activity. No mention is made of communication means to notify the patient that a change has occurred in his or her stomach activity. Because Foley et al. do not disclose this feature the teachings thereof do not anticipate claims 8 or 20 or the claims that depend from either of those claims, claims 18-22. Accordingly, withdrawal of the rejection of these claims is respectfully requested.

§ 103 Rejection of the Claims

Claims 7 and 10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clegg et al.’ 808 in view of Barreras et al., U.S. Patent no. 4,556,061. Applicant respectfully traverses this rejection.

The Examiner takes the position that Clegg et al. teach all the elements of the current invention except for an implanted alert module. For the reasons set forth above, Applicant respectfully disagrees that Clegg et al. teaches all the elements of the current invention. Furthermore, Barreras et al. do not teach sensing or monitoring any physiological parameters of a patient or communicating information to a patient about changes in such physiological parameters. The system of Barreras et al. is a battery consumption monitor system and the alarm is not generated as a function of a change in sensed physiological parameters. Clegg et al. teach external communication means and the use of an external data processor. Nowhere does the Clegg et al. disclosure teach or suggest that an implanted alert module would

be desirable. Accordingly, without access to Applicant's own disclosure, one of ordinary skill in the art would have had no appreciation of the desirability of such modification.

Claims 5 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clegg et al.' 808 in view of Bourgeois, U.S. Patent no. 5,836,994. Applicant respectfully traverses this rejection.

For the reasons discussed above, Applicant disagrees that Clegg et al. teaches all the elements of the claimed invention other than a method comprising measuring a second characteristic of a second physiological parameter as a function of a first characteristic of a first physiological parameter measured. The Examiner further takes the position that it would have been obvious to modify the method of Clegg et al. to include the use of a two sensor system described by Bourgeois. Bourgeois teaches the use of two sensors to sense gastric electrical activity. The sensors specifically sense electrical activity between a range of slow frequencies and the second sensor senses electrical activity at higher frequencies indicating spike activity. The sensors are used in providing electrical stimulation to the patient to treat patients having dysfunctional gastrointestinal muscle or disorders of smooth muscles. The method of Clegg et al. teaches the direct sensing of changes in a physiological parameter associated with changes in stomach activity, i.e., sensing spike activity which occurs upon normal peristaltic contractions. Nothing in Clegg et al. suggests that it would have been desirable to also sense a physiological parameter that precedes the physiological parameter of interest. Accordingly, without access to Applicant's own disclosure, one of ordinary skill in the art would have had no appreciation of the desirability of such modification.

In view of the foregoing amendments, Applicant respectfully requests reconsideration and allowance of the claims as all rejections have been overcome. Notice to this effect is kindly requested.

The Examiner is respectfully requested to contact the undersigned by telephone at

763.505.0003 or by E-mail at mary.p.bauman@medtronic.com with any questions or comments.

Respectfully submitted,

Date: August 17, 2006

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